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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/064,682	04/22/98	PETERSEN	J 273802002200

MORRISON & FOERSTER
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PALO ALTO CA 94304-1018

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EXAMINER

SWARTZ, R

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/064,682

Applicant(s)

Pedersen

Examiner

Rodney P. Swartz, Ph.D.

Group Art Unit

1641

☒ Responsive to communication(s) filed on 2 August 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) 21-26 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

R. P. Swartz 10-12-99
Rodney P. Swartz, Ph.D.
PATENT EXAMINER

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicant's Response to Restriction Requirement, received 2 August 1999, paper #8, is acknowledged. Applicant elected, without traverse, Invention I, claims 1-20, drawn to method of inducing tolerance. Claims 21-26 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b) as being drawn to a non-elected invention.
2. Currently, claims 1-20 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities: page 47, lines 6 and 7, "potentates" should be "potentiates".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1, 2, and 4-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the mucosal binding component, cholera toxin B (CTB), does not reasonably provide enablement for all mucosal binding components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification only teaches cholera toxin B subunit as the mucosal binding component in the working examples provided. The specification does not provide guidance for a person skilled in the art to substitute **all** mucosal binding components for CTB, as is encompassed within the scope of the instant claims, and achieve the claimed results.

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5. Claims 4, 6, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites that the components are “unassociated”. The specification teaches that “Two ‘unassociated’ molecules are neither conjugated nor associated.” (Page 14, lines 1-2). The specification teaches that two molecules are “associated” if, when the preparation is dissolved or diluted in 100 ml of isotonic buffer at pH ~7, at least 59% of the molecule not in excess is associated into a non-covalent heterodimer or heteropolymer of both molecules (page 13, lines 24-27). The definition of “associated” is unclear because the specification uses the word to be defined as the defining word, i.e., defines “associated” as a molecule being “associated”. Therefore, it remains unclear what is meant by “unassociated”.

Claim 6 recites that the inducing agent is a “bystander”. The specification does not define the term “bystander”.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP3109328 in view of Elson (*Current Topics in Microbiology*, 146:29-33, 1989).

The abstract of Japanese document JP3109328 supplied by applicant teaches that cholera toxin B subunit administered prior to administration of bone marrow cells results in prevention of transplant of the bone marrow. Therefore, the administration of the CTB is in an unconjugated form compared with the antigen. The document does not teach mucosal administration of the CTB by mucosal route.

Elson teaches that cholera toxin as an oral (i.e., mucosal) adjuvant when conjugated with an antigen, but that intestinal administration of mixtures of CTB plus antigen would not stimulate antibody response to the latter in the intestine or in serum.(page 31, first paragraph and second paragraph)

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to administer CTB as a mixture with an antigen to result in immunotolerance or immunosuppression of an immune response to said antigen.

Conclusion

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703)308-4027. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

Rodney P. Swartz
Rodney P. Swartz, Ph. D.
PATENT EXAMINER

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October 12, 1999